SEP 20 2004

K041491

## SECTION 16 510(K) SUMMARY

### 1. DATE PREPARED

June 2, 2004

### 2. SPONSOR INFORMATION

Zewa Inc.
Mr. Thomas Zeindler
3537 N.W. 115th Avenue
Miami, Florida 33178

(305) 463-7551 (telephone)
(305) 463-7553 (facsimile)

### 3. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | Zewa® MFM-007 Blood Pressure Monitor |
| Common/Usual Name: | MFM-007 Blood Pressure Monitor |
| Classification Name: | System, Measurement, Blood Pressure, Non Invasive |

### 4. DEVICE DESCRIPTION AND INTENDED USE

The Zewa® MFM-007 Blood Pressure Monitor is intended for use by adults with moderately active to inactive lifestyles for measuring the systolic and diastolic blood pressure, and pulse rate (heart rate) by using an inflated cuff which is wrapped around the upper arm.

### 5. PREDICATE DEVICE

It is substantially equivalent to the Meditec MD-800 Noninvasive Blood Pressure Measurement System cleared by FDA on July 21, 1999, under 510(k) K992328.

### 6. TECHNOLOGICAL CHARACTERISTICS

The Zewa® MFM-007 Blood Pressure Monitor measures the systolic and

diastolic blood pressure, and pulse rate (heart rate) by use of an inflatable cuff that is wrapped around the upper arm, a LCD display, a semiconductor sensor, and internal air pump, a battery power source and keys for operation.

## 7. DEVICE TESTING

The Zewa® MFM-007 Blood Pressure Monitor was tested for compliance with numerous technical specifications, including general performance under certain environmental conditions, influences of static electrical discharges, influences of irradiated electromagnetic field, and radio screening.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2004

Zewa, Inc.
c/o Mr. Thomas Zeindler
Vice President
3537 N.W. 115th Avenue
Miami, FL 33178

Re: K041491
Trade/Device Name: Zewa MFM-007 Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive blood pressure measurement system
Regulatory Class: II (two)
Product Code: DXN
Dated: June 2, 2004
Received: June 4, 2004

Dear Mr. Zeindler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K041491

Device Name: Zewa MFM-007 Blood Pressure Monitor

Indications For Use:

The Zewa MFM-007 Blood Pressure Monitor is intended for use by adults with moderately active to inactive lifestyles for measuring the systolic and diastolic blood pressure, and pulse rate (heart rate) by using an inflated cuff which is wrapped around the upper arm.

Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

B Gunnuma for

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041491